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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,003	07/16/2003	Li-Te Chin	16863-002001	1673

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EXAMINER	
WANG, LOUISE Z	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,003	CHIN, LI-TE	
	Examiner	Art Unit	
	Louise Wang	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 23-41* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 25-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24 and 36-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/06/04, 12/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner and location of your application in the Patent and Trademark Office have been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Wang, Art Unit 1648.

Election/Restrictions

Applicant's election without traverse of Group III, claims 23 and 24, and SEQ ID NO:3, in the reply filed on 20 September 2005 is acknowledged.

It is noted that applicant characterized SEQ ID NO:3 as a "species" in response to the Restriction Requirement sent by the previous examiner.

Claims 1-14 and 25-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 20 September 2005.

Since Applicant elected the process claim, Applicant is no longer entitled to the rejoinder of the process claims with the product claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b). Please see the prior Office Action for explanations.

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the amendment filed 20 September 2005. Claims 15-22 have been canceled. New claims 36-41 have been

added and drawn to the elected method. Therefore, claims 23, 24, and 36-41 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06 February 2004 and 17 December 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 24, and 36-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 23, 24, and 36-41 are directed to a method for preventing, treating or ameliorating an HIV infection comprising administering to a subject suffering from AIDS an effective amount of a composition comprising a fully human antibody, or an antigen binding fragment thereof, that recognizes at least two strains of HIV, wherein the antibody or fragment blocks HIV binding.

The instant claims do not identify any structural or functional characteristics of the claimed fully human antibody or fragment except that it recognizes the co-receptor binding region of gp120 or SEQ ID NO:3. The word "recognizes" does not specify the conditions and manners of the interaction between the epitope and the claimed antibody or fragment and thus does not define any function of the antibody or fragment. The word "subject" broadens the scope of the claimed genus and encompasses animals as well as humans; and thus, does not define the characteristic of the antibody. Further, the scope of the claimed genus of "antigen-binding fragment" is extending unlimitedly to any size fragment. Because the instant claims do not identify the claimed antibody or fragment by SEQ ID NO's, the general term "a fully human antibody or antigen-binding fragment thereof" is meaningless to the person of ordinary skill in the art in absence of support.

Therefore, the instant claims read on a method comprising administering human antibodies or fragments with no defined structure and the specification does not reasonably convey possession of these undefined antibodies or fragments.

Claims 23, 24, and 36-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 23, 24, and 36-41 are directed to a method for preventing, treating or ameliorating an HIV infection comprising administering to a subject suffering from AIDS an effective amount of a composition comprising a fully human antibody, or an antigen binding fragment thereof, that recognizes at least two strains of HIV, wherein the antibody or fragment blocks HIV binding.

The specification provides guidance only for preparing a specific trioma cell line stably secreting human IgG1 that recognize a pre-determined antigen. In other words, the invention is *in vitro* preparation of a human antibody or fragment that recognizes HIV at the coreceptor-binding site. The disclosure does not provide evidence for preventing, treating, or ameliorating an HIV infection with such a human antibody.

The specification rather provides the binding affinity data of the antibody LTC-gp120-IgG1k and an *in vitro* reverse transcriptase assay in the presence of the antibody (pages 30-31, Example 4, Figures 1-4). However, the clinical relevance of this measure is uncertain. An *in vitro* result of reduced activity of HIV reverse transcriptase is nowhere near an indication of the effectiveness of this antibody "for preventing, treating or ameliorating an HIV infection" as recited in the instant claims but a working hypothesis or speculation, because an *in vitro* system is over-simplified compared to the body of an AIDS subject and is improbable to fully capture the complex interactions of natural HIV infections in humans. Due to the highly unpredictable and complex nature of HIV-infection, results from *in vitro* studies such as enzyme activity assays and cell culture assays, *ex vivo* studies in SCID-hu xenograft models (Hsu, 2003), and *in vivo* studies in animal models and humans (Hu, 2005) don't always agree with each other.

Given the divergence of *in vitro* and *in vivo* HIV-specific immune responses, one skilled in the art would be burdened with a large quantity of *in vivo* experiments in order to make and use the current invention since the applicants have not provided any clear-cut evidence showing that the antibody LTC-gp120-IgG1k can prevent, treat, or ameliorate an HIV infection in an animal model.

Even if there is data to show that this antibody is capable of ameliorating an HIV infection *in vitro*, it is well known to one skilled in the art that this potential effect is soon thwarted by the rapid emergence of escape variants in an AIDS subject (Wei, 2003). Due to the high error rate of replication, HIV can evolve under immune pressure to evade the antibodies by making strategic alterations in the sequence and structure of its surface gp120. As a result, viral rebound is observed in treatment subjects within weeks after the administration, indicating ineffectiveness *in vivo* (Trkola, 2005). The specification does not address the problem of HIV mutation anywhere.

Considering the lack of data or working examples in application, the broad scope of the claims, the state and nature of the art, and the teachings regarding unpredictability in this art, the Applicant has not provided sufficient information to enable those skilled in the art to practice the claimed method without undue experimentation.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Wang, Ph.D.
Patent Examiner
19 October 2005

JEFFREY STUCKER
PRIMARY EXAMINER